

### REMARKS

This Amendment is in response to the Office Action mailed November 2, 2006 in the above captioned application. In the Office Action, Claims 1-24 were rejected over the prior art as discussed below. Claims 25-39 were previously withdrawn from consideration. In this Amendment, Claims 1, 6, 11, 14, and 20 have been amended, Claims 40-45 have been added, and Claim 2 has been canceled. No new matter has been added with these amendments. Claims 1, 3-24 and 40-45 are pending for further consideration.

#### Discussion of Embodiments of Cannulae of this Application

This application relates to cannulae capable of enhancing, maintaining, or providing for blood flow around the cannulae within the vasculature of a patient. In one embodiment, illustrated below in Figures 17 and 22 from the application, the cannula can comprise a balloon 704 that can be inflated to provide space between a vessel wall and the cannula. The balloon 704 can have a tubular configuration and also define a perfusion lumen 732, in some embodiments, when deployed. The perfusion lumen 732 can permit blood to flow therethrough when the balloon 704 has been deployed.

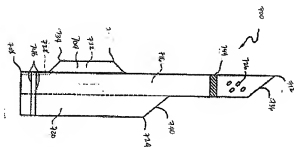


Fig. 17

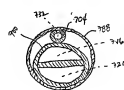


Fig. 22

In other embodiments, as illustrated below in Figure 18 from the application, a multilumen cannula can comprise a plurality of radially spaced balloons for enhancing, maintaining, or providing for blood flow. In some embodiments, such as those illustrated below, one lumen of the multilumen cannula can be longer than another lumen of the cannula.

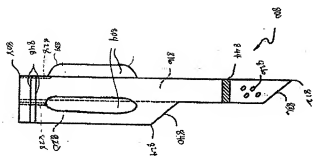


Fig. 18

In some embodiments, as illustrated below in Figure 19, a cannula can have an aperture and a sleeve carried by the cannula and moveable relative to the cannula to selectively cover and uncover the aperture to enhance, maintain, or provide for blood flow.

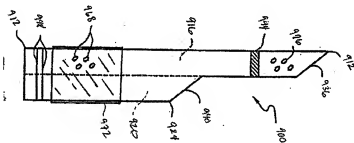


Fig. 19

#### Rejections Under 35 U.S.C. § 102

Claims 1-13 and 20-23 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,983,165 to Loiterman. Claims 14-18 were rejected as being anticipated by U.S. Patent No. 4,643,712 to Kulik et al. (Kulik).

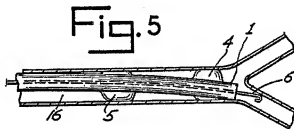
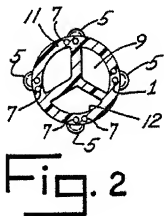
#### **Claim Rejections Based on Loiterman**

##### *Claims 1-5 Are Not Anticipated by Loiterman*

Claim 1 recites a perfusion cannula system for directing blood through the vasculature of a patient, comprising, among other limitations, a cannula body and a balloon located on an exterior surface of the cannula body. The balloon "has a tubular configuration that defines a

passive perfusion lumen when deployed.” When the cannula body resides within the patient, blood flow can be permitted through the passive perfusion lumen of the balloon. Loiterman does not disclose or suggest a cannula system as recited in Claim 1.

As illustrated below in Figures 2 and 5, Loiterman discloses a catheter that can be steered in different directions in the vasculature by selective inflation and deflation of aiming balloons 4, 5 positioned at various locations on the catheter. Loiterman does not disclose or suggest that the balloons 4, 5 are tubular or include a perfusion lumen. Furthermore, Loiterman does not disclose or suggest that blood can flow through a lumen defined by the inflation balloons. In contrast, Loiterman illustrates the aiming balloons as closed structures.



Loiterman (U.S. Patent No. 4,983,165)

For at least the reasons discussed above, Claim 1 is allowable over Loiterman. Claims 2-5 depend from Claim 1 and recite further limitations thereon. Claims 2-5 are therefore allowable for at least the reasons cited above with respect to Claim 1.

*Claims 6-10 Are Not Anticipated by Loiterman*

Claim 6 recites a perfusion cannula system for directing blood through the vasculature of a patient, comprising, among other limitations, a cannula body having “at least one blood flow lumen” extending between a proximal end and a distal end thereof for providing blood flow through the cannula body and means for creating space around the cannula body within the

vasculature "to permit passive perfusion blood flow" downstream from the cannula body. Loiterman fails to disclose or suggest the recited cannula system.

In contrast, as noted above, Loiterman discloses a catheter that is steerable by aiming balloons. Loiterman does not disclose a blood flow lumen for providing blood flow through the cannula body. Rather, Loiterman describes working channels 9 of the catheter (See. Fig. 2 above) that can include a guidewire, a laser, or "various wires, instruments, fiberoptic light bundles and flushing fluids." (Col. 3, lines 43-46; Col. 4, lines 44-46). Loiterman does not disclose or suggest that any of the working chambers can be used to provide blood flow, such as by withdrawing or delivering blood flow to the vasculature.

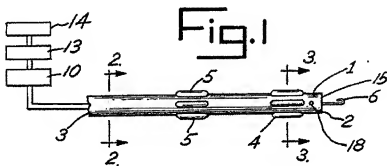
For at least the reasons discussed above, Claim 6 is allowable over Loiterman. Claims 7-10 depend from Claim 6 and recite further limitations thereon. Claims 7-10 are therefore allowable for at least the reasons cited above with respect to Claim 6.

*Claims 11-13 Are Not Anticipated by Loiterman*

Claim 11 recites a perfusion system for directing blood through the vasculature of a patient, comprising, among other limitations, a multilumen cannula having a first lumen having a first length for delivering or removing blood from the vasculature of the patient and a second lumen having a second length for delivering or removing blood from the vasculature of the patient, "the first length being greater than the second length." Loiterman does not disclose or suggest the perfusion system recited in Claim 11.

As illustrated in Figure 1 below, Loiterman describes a steerable catheter comprising a tubular member 1 with a proximal end 3 and a distal end 2. As illustrated above in Figure 2, the tubular member contains three working channels 9. As noted above, Loiterman does not disclose or suggest that the working channels are used to remove or deliver blood. All of the working channels extend substantially the entire length of the tubular member. Thus, in contrast to a multilumen catheter including, among other limitations, different length lumens for blood removal or delivery recited in Claim 11, Loiterman describes a catheter with equal length working channels that provide access for various tools. Moreover, Loiterman teaches away from having lumens of different lengths, by emphasizing the steerable nature of the catheter and the "extreme flexibility required to negotiate the vascular system." (Col. 2, lines 36-40). If the

working channels 9 of the Loiterman catheter had different lengths from one another, the exterior of the Loiterman catheter would be stepped, which could limit the ability of the catheter to be steered in the vasculature.



Loiterman (U.S. Patent No. 4,983,165)

For at least the reasons discussed above, Claim 11 is allowable over Loiterman. Claims 12-13 depend from Claim 11 and recite further limitations thereon. Claims 12-13 are therefore allowable for at least the reasons cited above with respect to Claim 11.

*Claims 20-23 Are Not Anticipated by Loiterman*

Claim 20 recites a perfusion cannula system comprising, among other limitations, a cannula body comprising “a means for providing blood flow to the vasculature of a patient,” and a means for enhancing blood flow past the cannula when the cannula body resides within the patient. Loiterman fails to disclose or suggest the perfusion cannula system recited in Claim 20.

As noted above with respect to Claims 6 and 11, Loiterman discloses a steerable catheter having working channels therein. Loiterman describes using the working channels to transport various devices to a portion of the vasculature. The catheter described by Loiterman therefore does not disclose nor suggest “a means for providing blood flow to the vasculature of a patient,” as recited in Claim 20.

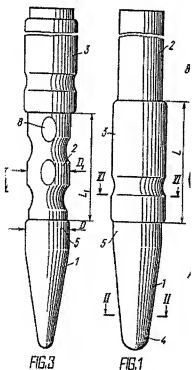
For at least the reasons discussed above, Claim 20 is allowable over Loiterman. Claims 21-23 depend from Claim 20 and recite further limitations thereon. Claims 21-23 are therefore allowable for at least the reasons cited above with respect to Claim 20.

### Claim Rejections Based on Kulik

### Claims 14-18 Are Not Anticipated by Kulik

Claim 14 recites a perfusion cannula system, comprising, among other limitations, a cannula comprising a cannula body having an aperture formed therein and a sleeve carried by the cannula. The sleeve is configured to be moveable relative to the aperture “to selectively cover and uncover the aperture as desired when the cannula body resides within the patient.” Kulik does not disclose or suggest the claimed perfusion cannula system.

As illustrated below in Figures 1 and 3, Kulik describes an aortic return cannula having a plurality of perforations at one end thereof. The cannula includes a slideable sleeve 3 that initially covers the perforations (as in Figure 1), and is automatically slid back a single time as the cannula is advanced into the aorta (as in Figure 3). (Col. 3, lines 51-66). Once the cannula is advanced into the aorta, “the sleeve remains immovable and forced against the aortic wall.” (Col. 3, lines 61-62). Thus, Kulik does not disclose or suggest a sleeve configured to selectively *cover and uncover* an aperture as desired *when the cannula body resides within the patient*. Rather, once the Kulik device has been advanced into the aorta, uncovering the perforations, the perforations can not be selectively covered.



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For at least the reasons discussed above, Claim 14 is allowable over Kulik. Claims 15-18 depend from Claim 14 and recite further limitations thereon. Claims 15-18 are therefore allowable for at least the reasons cited above with respect to Claim 14.

Rejections Under 35 U.S.C. § 103

Under 35 U.S.C. § 103(a), Claim 19 was rejected in the Office Action as obvious in view of Kulik and Loiterman, and Claim 24 was rejected as obvious in view of Loiterman and U.S. Patent No. 6,475,187 to Gerberding.

*Claim 19 is Distinguishable over Kulik in View of Loiterman*

Claim 19 depends from Claim 14 and recites that the perfusion cannula system further comprises a second lumen. The Examiner indicated that Kulik does not disclose a second lumen, but that Loiterman discloses this feature. As noted above with respect to Claim 14, Kulik fails to disclose or suggest all of the claim limitations recited therein. Loiterman does not provide the limitation of Claim 14 not found in Kulik. Therefore, the combination of Kulik with Loiterman suggested by the Examiner fails to disclose or suggest all of the features recited in Claim 19.

*Claim 24 is Distinguishable over Loiterman in View of Gerberding*

Claim 24 depends from Claim 20 and recites that the enhancing means of the cannula body comprises, among other limitations, at least one aperture in the cannula body, and a sleeve carried by the cannula. The Examiner indicated that Loiterman fails to disclose a sleeve disposed on the cannula body, but that Gerberding discloses a sleeve.

As noted above with respect to Claim 20, Loiterman fails to disclose or suggest all of the recited limitations. Gerberding does not provide the limitation of Claim 20 not found in Loiterman. Therefore, the combination of Loiterman and Gerberding suggested by the Examiner fails to disclose all of the elements of Claim 24, which depends from Claim 20.

New Claims 40-45

Applicants have added Claims 40-45 in this Response. Claims 40-41 depend from Claim 1 and recite additional limitations thereon. Therefore, Claims 40-41 are allowable for at least the

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reasons discussed above with respect to Claim 1. Claims 42-45 depend from Claim 14 and recite additional limitations thereon. Therefore, Claims 42-45 are allowable for at least the reasons discussed above with respect to Claim 14. No new matter has been added with these amendments.

### CONCLUSION

In view of the foregoing, Applicants respectfully submit that all pending claims of the present application are in condition for allowance, and such action is earnestly solicited. If, however, any questions remain, the Examiner is cordially invited to contact the undersigned so that any such matter may be promptly resolved.

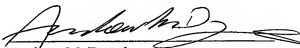
Applicants respectfully traverse the Examiner's rejections and the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: May 2, 2007

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